Application No.: 10/684,778
Filing Date: 10/14/2003
Docket No.: 5746/B

REMARKS

Claims 31, 34-41 and 48-55 are pending.

Claims 31, 48 and 51 have been amended to require a stabilizing agent selected from the group consisting of xanthan gum, locust bean gum and carrageenan. Claim 31 has been additionally amended to change "anti-diaherrals" to "anti-diarrheals". Support for the amendment can be found at paragraphs 0094 and 0110 of US Patent Application Publication 20040136922.

Claim Objections:

Claims 31 and 34-41 are objected to because of the following informalities: the word "anti-diaherrals" in claim 31 appears to spell as anti-diarrhea. Further clarification is suggested. Applicants have corrected the misspelled word "anti-diaherrals" to read "anti-diarrheals". This should obviate the Examiner's objection.

Double Patenting:

Claims 31, 34-41 and 48-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of USPN 6,596,298 ('298) or claims 1 and 6 of USPN 6,923,981 ('981), in view of Kulkarni et al. US 2003/0211136. Applicants respectfully traverse this rejection submit herewith a terminal disclaimer over '298 and '981. This should obviate the Examiner's rejection. Both '298 and '981 were issued from US Patent application serial number 09/395,104 (App. '104). The patent application US Patent application serial number 10/081,018 (filed February 21, 2002) is a divisional filed as a result of a restriction requirement in App. '104 and before the issuance of '298 and '981. 35 USC 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. (MPEP 804.01). Therefore, the double patenting rejection with respect to '298 and '981 is improper and Applicants respectfully ask that it be withdrawn.

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Claim Rejections:

Claims 31, 34 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/17753 (US equivalent 6,906,043) to Awamura, et al. (Awamura). Applicants respectfully traverse this rejection.

Awamura relates to rapidly soluble film preparations mainly comprising a drug, an edible polymer and a saccharide, a manufacturing method of which is simple, and having high elution rate. Importantly, Awamura nowhere mentions the use of gums as stabilizing agents. In contrast, the compositions of the present invention, as amended, are directed to consumable film adapted to rapidly dissolve in the mouth of a consumer, wherein said film comprises a single layer including pullulan, a stabilizing agent selected from the group consisting of xanthan gum, locust bean gum and carrageenan and select pharmaceutical agents. Therefore, since Awamura fails to mention the use of gums as stabilizing agents, the compositions of the present invention, as amended, would not be anticipated, nor would they have been obvious over this reference.

Claims 31, 34-41 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Awamura in view of US 2003/0211136 to Kulkarni et al. (Kulkarni). Applicants respectfully traverse this rejection.

The present application has a priority date of September 25, 1998 (actually claiming priority to the same provisional application as Kulkarni - Provisional Application Serial No. 60/101,798). Therefore, Kulkarni is not relevant as prior art. And, as discussed above, since Awamura fails to mention the use of gums as stabilizing agents, the compositions of the present invention, as amended, would not have been obvious over Awamura and Kulkarni in combination.

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In light of the remarks made herein, it is respectfully submitted that the Examiner's rejection under 35 USC §§102 and 103 have been overcome. Applicants respectfully submit that they have distinguished the cited art sufficiently to avoid the Examiner's rejection. Accordingly, reconsideration and allowance of Claims 31, 34-41 and 48-55 are earnestly solicited.

Date

6/21/06

Respectfully submitted,

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